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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,034	11/24/2003	T. Douglas Mast	END-5042USCIP	4797

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EXAMINER	
ROY, BAISAKHI	
ART UNIT	**PAPER NUMBER**
3737	

MAIL DATE	DELIVERY MODE
08/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,034	MAST ET AL.	
	Examiner	Art Unit	
	BAISAKHI ROY	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/1/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/1/09 has been entered.

Inventorship

2. In view of the papers filed 11/8/04, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by addition of Waseem Faidi, Inder Raj S. Makin, Peter G. Barthe, and Michael H. Slayton as coinventors.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7211044. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to a method for mapping or ultrasonically scanning a condition such as temperature in a patient and obtaining a second scan of the region of interest once it has undergone medical treatment. The steps further include generating a difference signal between the first and second signal and creating an image of the difference signal which shows the effects of medical treatment and in this case show the temperature rise occurring the anatomical tissue. The patented claims are directed to a more specific form of medical treatment and use the method in the current application to monitor the effects of a treatment on a tissue ultrasonically. Therefore the patented claims anticipate the claims of current application.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1- 4, 6-8, 10-22, 24-27, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grucar et al. (6030344) in view of Arditi (5526816).

Grucar et al. disclose a method for ultrasound imaging by positioning an ultrasound transducer 104, 430 relative to an anatomical tissue or blood cells or tissue. This is followed by receiving and processing a time-varying first signal of first set of image frames of a first imaging ultrasound wave which has been reflected from a location in the anatomical tissue during a first time period (col. 3 lines 40-42). Then the process involves receiving and processing a time-varying second signal or second set of image frames of a second imaging ultrasound wave which has been reflected from the location in the anatomical tissue at a later second time period (col. 3 lines 43-48). The patient is treated with a contrast agent and images are obtained over time both before and after the introduction of the contrast agent (col. 6 lines 46-col. 7 line 3). Therefore images are obtained over time both before and after a treatment procedure.

Grucar et al. do not teach the step of subtracting the second signal from the first signal. In the same field of endeavor Arditi discloses a system and method of B-Mode ultrasonic imaging of organs and tissue (col. 11 lines 22-32) by detection of ultrasound backscatter of a region containing contrast agent using a real-time method in which

ultrasound beams are projected to a zone of the tissue to be imaged and echoes reflected from the tissue and received and processed through two independent channels with pass-bands tuned at selected frequencies (col. 3 lines 39-49). Frequencies are selected such that the differences between the amplitude of echoes reflected from tissue containing contrast agent and that of echoes reflected by the tissue itself (without contrast agent) is maximal (col. 6 lines 22-26). The method involves subtracting the signals to provide a maximal difference of processed signal amplitude resulting from echoes reflected from tissue containing contrast agent and that of echoes reflected by tissue without contrast agent (col. 6 lines 36-52). The signals may be received and processed both before and after the administration of contrast agent has been completed. The difference signal undergoes filtering by passing the signals through different bandpass filters (col. 10 lines 1-14). The difference signal is scaled by squaring the amplitude of the output or difference signal where S(f) can be replaced by its square S^2 (f) (col. 7 lines 3-10). The calculations include computing the average of the signals and using the average of the signals to generate an indication showing the effect of the contrast treatment (col. 7 lines 3-15).

Arditi teach administering the contrast agent to the patient and then only certain sections of tissue are perfused by contrast agent while other sections might be inaccessible to the contrast agent and the ultrasound wave will pass through segments or sections perfused with contrast agent and sections not perfused with contrast agent (col. 5 lines 52-63). Therefore the contrast agent is always present in different anatomical locations but the image shows perfused and non-perfused areas based on

the affinity of the anatomical site for the contrast agent. The contrast agent or treatment is thus administered to different locations of anatomical tissue and the final image includes contrast-enhanced or medically treated locations and non-perfused or medically untreated locations.

Therefore Arditi teaches a method for measuring the difference between signal affected by treatment and signal unaffected by treatment over a period of time. It would have therefore been obvious to one of ordinary skill in the art to modify Grucar et al. such that the difference between the first signal obtained at a first time period prior to treatment with contrast agent and the second signal obtained at a second time period after treatment with contrast agent to provide a signal indicating the effect of the treatment or contrast agent over time.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grucar et al. al. in view of Arditi as applied to claims above, and further in view of Robinson et al. (6315723). Grucar et al. and Arditi teaches reducing noise in the images but do not explicitly teach the use of a phase compensation function. In the same field of endeavor Robinson et al. disclose an ultrasound system and method where ultrasound signals with different transmit focal characteristics are processed to synthesize the characteristics of an extended transmit focal zone (col. 1lines 62-col. 2 line 6). Figures 8b and 9b illustrate the use of a phase compensation function or characteristic for the echo signal (col. 7 lines 66-col. 8 lines 19) from the different focused scanlines which are combined to form an extended focus scanline. This causes the axial resolution to be improved and increase on-axis response while reducing undesired cancellation

resulting from the combining of locationally misaligned signals of the combined scanlines. It would have therefore been obvious to one or ordinary skill in the art to use the teaching by Robinson et al. to modify the teaching by Grucar et al. and Arditi such that noise and motion artifacts are reduced.

8. Claims 9, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grucar et al. in view of Arditi as applied to claims above, and further in view of Fujimoto et al. (6540700).

Grucar et al. and Arditi both teach the use of a contrast agent as a treatment procedure and do not teach explicitly ultrasound medical treatment. In the same field of endeavor Fujimoto et al. disclose an ultrasound treatment/imaging system and method where treatment ultrasound is alternately generated and stopped and ultrasound imaging is intermittently executed with stop periods of treatment ultrasound (col. 3 lines 50-62). Image is obtained before and after treatment and there are differences in intensity before irradiation of treatment ultrasound among patients and then the changes in intensity are monitored over time (col. 20 lines 1-12). The initial B-mode image is obtained before treatment and then over time, images are generated indicating the affects of the treatment (col. 20 lines 42-60). Since the contrast treatment in both Grucar et al. and Arditi are directed to ultrasonically monitoring the effects of contrast agent treatment over time, it would be obvious to substitute an ultrasound-based treatment procedure, as disclosed in Fujimoto et al., in place of the contrast treatment to ultrasonically treat a patient and effectively monitor the treatment results on the anatomical site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR
/Baisakhi Roy/
Examiner, Art Unit 3737